Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® for imaging work-up for stage I breast carcinoma.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Women's Imaging-Breast Work Group. Imaging work-up for stage I breast carcinoma. Reston (VA): American College of Radiology (ACR); 2002. 4 p. (ACR appropriateness criteria). [28 references]

GUIDELINE STATUS

This is the current release of the guideline. It updates a previously published version: Imaging work-up for stage I breast carcinoma. American College of Radiology (ACR). ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):955-9.

The ACR Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The anticipated next review date for this topic is 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Stage I breast carcinoma

GUIDELINE CATEGORY

Evaluation
Screening

CLINICAL SPECIALTY

Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic examinations for the imaging work-up of patients with Stage I breast carcinoma

TARGET POPULATION

Patients with Stage I breast carcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

1. Radiographic survey
2. Radionuclide scanning
3. Magnetic resonance imaging (MRI)
4. Chest radiography
5. Conventional tomography
6. Computed tomography (CT)
7. Ultrasonography
8. Computed tomography with contrast

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and

weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Stage I Breast Carcinoma

Variant: Rule out metastases - asymptomatic woman.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Rule Out Bone Metastases		
Radiographic survey	2	
Radionuclide scanning	2	
MRI	2	
Rule Out Thoracic Metastases		
Chest radiography	2	
Conventional tomography	2	
CT	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Rule Out Liver Metastases		
Radionuclide scanning	2	
Ultrasonography	2	
MRI	2	
CT	2	
Rule Out Brain Metastases		
Radionuclide scanning	2	
Computed tomography	2	
CT with contrast	2	
MRI	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: MRI, magnetic resonance imaging; CT, computed tomography

Summary

Staging parameters for breast cancer according to the TMN classification of the American Joint Committee on Cancer include T, the local extent of disease; N, the presence of regional lymph node metastases; and M, the presence of distant metastases. A diagnosis of Stage I breast cancer indicates surgical removal of an invasive breast carcinoma that is 2 cm or smaller in diameter (T1), which has no regional (axillary) lymph node metastases (N0), and no distant metastases (M0).

The most common sites for distant metastases from breast carcinoma are the skeleton, lung, liver, and brain. Several imaging examinations are available that can potentially identify metastases to these various organs. Surveys of patients with breast cancer indicate that most of these patients prefer an intensive follow-up to detect asymptomatic disease, including metastases. Surveys of physicians who take care of patients with breast cancer indicate that most of these physicians also favor intensive surveillance programs of patients with breast cancer who are asymptomatic. However, because of cost constraints, there should be a reasonable anticipated yield and an expected effect on patient management and outcome when imaging examinations are ordered on asymptomatic patients with breast cancer. This appropriateness guideline segment addresses the imaging work-up of women with Stage I breast carcinoma, specifically which imaging tests should be done to rule out unexpected metastatic disease.

Skeletal Metastases

Radionuclide scanning is more effective than conventional radiography for the detection of skeletal metastases because radionuclide scans have higher sensitivity and can survey the entire skeleton in one examination. However, several investigations that are discussed in the original guideline document have revealed that bone scanning is not useful in Stage I breast carcinoma because of the low yield of the examination as well as a lack of proven effect on management or survival.

Lung Metastases

Methods for detecting lung metastases include conventional chest radiography and computed tomography (CT). Because of its relatively low cost when compared with the other imaging modalities, conventional chest radiography is considered the most reasonable approach for detection of unsuspected disease, as a baseline for monitoring, and for routine follow-up. Computed tomography is more sensitive than conventional whole-lung tomography and is the method of choice to evaluate equivocal findings on chest radiography and to identify additional nodules in positive cases.

Despite its relatively low cost, investigators have even questioned the use of routine chest radiography to detect intrathoracic metastases in patients with breast cancer, especially those with Stage I disease. One problem is the low yield in Stage I disease, reported at less than 0.5% in asymptomatic women who had routine chest x-rays after the diagnosis of Stage I breast carcinoma. Furthermore, false-positive chest radiographs can lead to expensive diagnostic work-ups. Two large Italian randomized control studies failed to show a significant outcome benefit when routine chest radiography was used to detect metastases earlier.

Liver Metastases

Both radionuclide scanning and ultrasonography have been used to detect liver metastases. Although liver metastases are not as common as lung or bone metastases, the appearance of liver metastases is associated with the worst prognosis. To be detected reliably by Tc-99m sulfur colloid liver scans, metastases generally must be greater than 2 cm. Ultrasonography can also identify liver metastases 2 cm or larger, and is often used to localize these lesions for biopsy or fine-needle aspiration cytology.

As with screening for bone and lung metastases, the yield of screening with radionuclide scans or ultrasonography for detection of asymptomatic liver metastases is low.

Although CT and magnetic resonance imaging (MRI) may show more lesions than radionuclide scanning or ultrasonography, there is no evidence in the literature that routine imaging of the liver with either of the more sensitive modalities has clinical utility in asymptomatic patients with breast carcinoma.

Brain Metastases

Breast cancer is second only to lung carcinoma as a cause of intracerebral and orbital metastases, but few patients have brain metastases at the time of breast

cancer diagnosis, particularly when the tumor is detected at Stage I. In CT examinations, brain metastases may be nodular or ring-shaped, single, or multiple; are usually associated with extensive edema; and show varying amounts of enhancement with intravenous contrast agents. One review of patients with breast cancer at all stages having radionuclide brain scanning and CT found that imaging studies failed to identify brain metastases in the absence of neurologic symptoms. Because of its greater sensitivity, MRI has largely replaced CT for the detection and evaluation of brain lesions. Gadolinium-enhanced magnetic resonance imaging increases the number of suspected cerebral metastases that can be detected. Contrast-enhanced MRI has also been shown to be superior to double-dose delayed CT for detection of brain metastases. However, no studies suggest any usefulness to routine imaging with any modality for the detection of cerebral metastases in asymptomatic women with breast cancer.

Refer to the original guideline document for a discussion of quality of life issues.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for Stage I breast carcinoma

POTENTIAL HARMS

Radionuclide Scanning for Skeletal Metastases

Several studies have reported false-positive scans as a problem encountered when screening for metastases in asymptomatic patients.

Routine Chest Radiography for Lung Metastases

False-positive chest radiographs can lead to expensive diagnostic work-ups.

Radionuclide Scanning and Ultrasonography for Liver Metastases

In one retrospective study of 234 asymptomatic patients with breast cancer at various stages, 8 of 11 positive scans were eventually determined to be false-positives.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2002)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Women's Imaging-Breast Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Lawrence Bassett, MD; Marcela Bohm-Velez, MD; Gilda Cardenosa, MD; Carl D'Orsi, MD; W. Phil Evans III, MD; Ellen Mendelson, MD; Amy Thurmond, MD; Steven Goldstein, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 30, 2001. The information was verified by the guideline developer as of February 20, 2001. This summary was updated by ECRI on March 31, 2003. The updated information was verified by the guideline developer on April 21, 2003.

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DISCLAIMER

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Date Modified: 9/25/2006